

Amendment No.

COMMITTEE/SUBCOMMITTEE ACTION

ADOPTED	<u> </u>	(Y/N)
ADOPTED AS AMENDED	<u> </u>	(Y/N)
ADOPTED W/O OBJECTION	<u> </u>	(Y/N)
FAILED TO ADOPT	<u> </u>	(Y/N)
WITHDRAWN	<u> </u>	(Y/N)
OTHER	<u> </u>	

1 Committee/Subcommittee hearing bill: Health & Human Services
 2 Committee
 3 Representative Busatta Cabrera offered the following:

Amendment

Remove lines 54-260 and insert:

7 (a) There is created a cause of action for an ex parte
 8 temporary injunction against continued unlicensed activity by a
 9 person or entity violating subsection (1), not to exceed 30
 10 days.

11 (b) A sworn petition seeking an ex parte temporary
 12 injunction against continued unlicensed activity shall allege
 13 the following:

- 14 1. The location of the unlicensed activity;
- 15 2. The names of the owners and operators of the unlicensed
 16 provider;

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17 3. The type of services that require licensure;

18 4. Specific facts supporting the conclusion that the
19 unlicensed provider is engaged in unlicensed activity, including
20 the date, time, and location at which the unlicensed provider
21 was notified by the agency to discontinue such activity;

22 5. That agency personnel have verified, through an onsite
23 inspection, that the unlicensed provider is advertising,
24 offering, or providing services that require licensure;

25 6. Whether the unlicensed provider prohibited the agency
26 from conducting a subsequent investigation to determine current
27 compliance with applicable laws and rules;

28 7. Any previous injunctive relief granted against the
29 unlicensed provider; and

30 8. Any previous agency determination that the unlicensed
31 provider has been identified as engaging in unlicensed activity.

32 (c) A bond may not be required by the court for entry of
33 an ex parte temporary injunction.

34 (d) Except as provided in s. 90.204, in a hearing to
35 obtain an ex parte temporary injunction, evidence other than
36 verified pleadings or affidavits by agency personnel or others
37 with firsthand knowledge of the alleged unlicensed activity may
38 not be used as evidence, unless the unlicensed provider appears
39 at the hearing. A denial of a petition for an ex parte
40 temporary injunction shall specify the grounds for denial in
41 writing.

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42 (e) If the court determines that the unlicensed provider
43 is engaged in continued unlicensed activity after agency
44 notification to cease such unlicensed activity, the court may
45 grant the ex parte temporary injunction restraining the
46 unlicensed provider from advertising, offering, or providing
47 services for which licensure is required. The court may also
48 order the unlicensed provider to provide to agency personnel
49 access to personnel, records, and clients for future inspection
50 of the unlicensed provider's premises.

51 (f) The agency must inspect the unlicensed provider's
52 premises within 20 days of entry of the ex parte temporary
53 injunction to verify compliance with such injunction. If the
54 unlicensed provider is complying, the agency shall dismiss the
55 injunction. If unlicensed activity has continued, the agency
56 may file a petition for permanent injunction within 10 days of
57 identifying noncompliance. The agency may also petition to
58 extend the ex parte temporary injunction until the permanent
59 injunction is decided.

60 (g) The agency may provide any inspection records to law
61 enforcement or a state attorney's office upon request and
62 without redaction.

63 Section 3. Paragraphs (a) and (e) of subsection (1) of
64 section 458.328, Florida Statutes, are amended and subsection
65 (2) renumbered as subsection (3), and a new subsection (2) is
66 added to that section to read:

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67 458.328 Office surgeries.—

68 (1) REGISTRATION.—

69 (a) An office in which a physician performs a liposuction
70 procedure in which more than 1,000 cubic centimeters of
71 supernatant fat is removed, a Level II office surgery, or a
72 Level III office surgery must register with the department
73 ~~unless the office is licensed as a facility under chapter 390 or~~
74 ~~chapter 395.~~ The department must inspect any such office prior
75 to registration. The department may not register a facility
76 that must be licensed under chapter 390 or chapter 395.

77 (e) The department shall inspect a registered office at
78 least annually, including a review of patient records, to ensure
79 that the office is in compliance with this section and rules
80 adopted hereunder unless the office is accredited by a
81 nationally recognized accrediting agency approved by the board.
82 The inspection may be unannounced, except for the inspection of
83 an office that meets the description of a clinic specified in s.
84 458.3265(1)(a)3.h., and those wholly owned and operated
85 physician offices described in s. 458.3265(1)(a)3.g. which
86 perform procedures referenced in s. 458.3265(1)(a)3.h., which
87 must be announced. The department must refuse to register a new
88 office or immediately suspend the registration of a registered
89 office that refuses an inspection for 14 days and the office
90 must be closed during the period of suspension. The suspension

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91 must remain in effect until the department has completed its
92 inspection.

93 (2) STANDARD OF PRACTICE.-

94 (a) For purposes of this section, the term:

95 1. "Office surgery" means a surgery performed at an office
96 that primarily serves as a physician's office at which a
97 physician regularly performs consultations with surgical
98 patients, presurgical examinations, and postoperative monitoring
99 and care related to office surgeries and at which patient
100 records are readily maintained and available.

101 2. "Physician" means a physician or surgeon licensed to
102 practice under this chapter.

103 (b) A physician performing a gluteal fat grafting
104 procedure in an office surgery setting shall adhere to standards
105 of practice under this subsection and rules adopted by the
106 board.

107 (c) Office surgeries may not:

108 1. Result in blood loss of more than 10 percent of
109 estimated blood volume in a patient with a normal hemoglobin
110 level;

111 2. Require major or prolonged intracranial, intrathoracic,
112 abdominal, or joint replacement procedures, except for
113 laparoscopic procedures;

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114 3. Involve major blood vessels performed with direct
115 visualization by open exposure of the major blood vessel, except
116 for percutaneous endovascular intervention; or

117 4. Be emergent or life threatening.

118 (d)1. A physician performing a gluteal fat grafting
119 procedure must be a board-eligible or board-certified plastic
120 surgeon.

121 2. The physician performing a gluteal fat grafting
122 procedure must conduct an in-person examination of the patient
123 no later than 24 hours prior to the procedure.

124 3. Any duty delegated by a physician, with a patient's
125 informed consent, to be performed during a gluteal fat grafting
126 procedure must be performed under the direct supervision of the
127 physician performing such procedure. Gluteal fat injections
128 must be performed by the physician and may not be delegated.

129 4. Gluteal fat may only be injected into the subcutaneous
130 space of the patient and may not cross the fascia overlying the
131 gluteal muscle. Intramuscular or submuscular fat injections are
132 prohibited.

133 5. When the physician performing a gluteal fat grafting
134 procedure injects fat into the subcutaneous space of the
135 patient, the physician must use ultrasound guidance during the
136 placement and navigation of the canula to ensure that the fat is
137 injected into the subcutaneous space of the patient above the
138 fascia overlying the gluteal muscle. The board may establish

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139 minimum technical standards for such ultrasound guidance.
140 Ultrasound guidance is not required for other portions of such
141 procedure.

142 (e) If a procedure in an office surgery setting results in
143 hospitalization, the type of procedure performed and the
144 location at which the procedure was performed, if known, must be
145 included in the hospital intake information for the purpose of
146 adverse incident reporting.

147 Section 4. Paragraphs (a) and (e) of subsection (1) of
148 section 459.0138, Florida Statutes, are amended and subsection
149 (2) renumbered as subsection (3), and a new subsection (2) is
150 added to that section to read:

151 459.0138 Office surgeries.—

152 (1) REGISTRATION.—

153 (a) An office in which a physician performs a liposuction
154 procedure in which more than 1,000 cubic centimeters of
155 supernatant fat is removed, a Level II office surgery, or a
156 Level III office surgery must register with the department
157 ~~unless the office is licensed as a facility under chapter 390 or~~
158 ~~chapter 395.~~ The department must inspect any such office prior
159 to registration. The department may not register a facility
160 that must be licensed under chapter 390 or chapter 395.

161 (e) The department shall inspect a registered office at
162 least annually, including a review of patient records, to ensure
163 that the office is in compliance with this section and rules

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164 adopted hereunder unless the office is accredited by a
165 nationally recognized accrediting agency approved by the board.
166 The inspection may be unannounced, except for the inspection of
167 an office that meets the description of clinic specified in s.
168 459.0137(1)(a)3.h., and those wholly owned and operated
169 physician offices described in s. 459.0137(1)(a)3.g. which
170 perform procedures referenced in s. 459.0137(1)(a)3.h., which
171 must be announced. The department must refuse to register a new
172 office or immediately suspend the registration of a registered
173 office that refuses an inspection for 14 days and the office
174 must be closed during the period of suspension. The suspension
175 must remain in effect until the department has completed its
176 inspection.

177 (2) STANDARD OF PRACTICE.-

178 (a) For purposes of this section, the term:

179 1. "Office surgery" means a surgery performed at an office
180 that primarily serves as a physician's office at which a
181 physician performs surgeries as permitted under this section.
182 The physician's office must be an office at which such physician
183 regularly performs consultations with surgical patients,
184 presurgical examinations, and postoperative monitoring and care
185 related to office surgeries and at which patient records are
186 readily maintained and available.

187 2. "Physician" means a physician or surgeon licensed to
188 practice under this chapter.

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189 (b) A physician performing a gluteal fat grafting
190 procedure in an office surgery setting shall adhere to standards
191 of practice under this subsection and rules adopted by the
192 board.

193 (c) Office surgeries may not:

194 1. Result in blood loss of more than 10 percent of
195 estimated blood volume in a patient with a normal hemoglobin
196 level;

197 2. Require major or prolonged intracranial, intrathoracic,
198 abdominal, or joint replacement procedures, except for
199 laparoscopic procedures;

200 3. Involve major blood vessels performed with direct
201 visualization by open exposure of the major blood vessel, except
202 for percutaneous endovascular intervention; or

203 4. Be emergent or life threatening.

204 (d)1. A physician performing a gluteal fat grafting
205 procedure must be a board-eligible or board-certified plastic
206 surgeon.

207 2. The physician performing a gluteal fat grafting
208 procedure must conduct an in-person examination of the patient
209 no later than 24 hours prior to the procedure.

210 3. A duty delegated by a physician, with a patient's
211 informed consent, to be performed during a gluteal fat grafting
212 procedure must be performed under the direct supervision of the

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213 physician performing such procedure. Gluteal fat injections
214 must be performed by the physician and may not be delegated.

215 4. Gluteal fat may only be injected into the subcutaneous
216 space of the patient and may cross the fascia overlying the
217 gluteal muscle. Intramuscular or submuscular fat injections are
218 prohibited.

219 5. When the physician performing a gluteal fat grafting
220 procedure injects fat into the subcutaneous space of the
221 patient, the physician must use ultrasound guidance during the
222 placement and navigation of the canula to ensure that the fat is
223 injected into the subcutaneous space of the patient above the
224 fascia overlying the gluteal muscle. The board may establish
225 minimum technical standards for such ultrasound guidance.
226 Ultrasound guidance is not required for other portions of such
227 procedures.

228 (e) If a procedure in an office surgery setting results in
229 hospitalization, the type of procedure performed and the
230 location at which the procedure was performed, if known, must be
231 included in the hospital intake information for the purpose of
232 adverse incident reporting.